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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/916,214	07/25/2001	Theodore C. Johnson	37167-8040.US00	6833

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EXAMINER	
PEFFLEY, MICHAEL F	

ART UNIT	PAPER NUMBER
3739	

DATE MAILED: 06/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/916,214	JOHNSON ET AL.	
	Examiner	Art Unit	
	Michael Peffley	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *38-71* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *38-71* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 12, 2004 has been entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 38-71 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The recitation added to claim 38 is deemed to present new matter. In particular, the specification, as originally filed, does not provide explicit support for providing each sensor member with a separate energy source. Applicant referenced page 36, lines 24-27 and page 37, lines 7-11 to support the added limitations. The examiner could find

nothing on page 36 to support the use of separate energy sources for each sensor member. The recitation on page 37 suggests the use of different frequency energy sources (line 5), and that the electrodes may be isolated to allow for separate frequencies for each electrode (lines 7-9), but does not expressly state that there is a separate energy source for each electrode. It is noted that a multiplexing circuitry is used to couple the energy sources to the electrodes. Moreover, the recitation at page 37 is directed towards energy sources connected to electrodes, and not energy sources connected to sensor members. There is nothing in the specification that suggests that an energy source is connected to a sensor member, per se. It is noted that the specification suggests that the resilient members may function solely as a sensor, or may be an electrode with a sensor thereon.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 38-71 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation of the separate energy sources coupled to each sensor member, and of electrodes coupled to at least one energy source is confusing. In particular, it is not clear why a resilient member functioning solely as a sensor member would need to be connected to an energy source. Also, it is not clear if the "separate energy source" connected to each sensor member is separate from the "at least one energy source" which may be connected to the electrodes.

Claim Rejections - 35 USC § 102

Claims 38-42 and 45-71 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Gough et al ('384).

Gough et al provide a device which comprises an elongate delivery device (18) maneuverable in tissue, and a plurality of resilient members (16) which are deployable into tissue with curvature. The resilient members are RF electrodes which may be used to treat tissue, and the electrodes include sensors (24) for measuring tissue impedance and using that measurement to monitor the ablation of tissue and control the delivery of RF energy. A multiplexer is used to control the delivery of data between the multiple resilient members (see col. 9, lines 37-40). Resources are provided for using the impedance data to control the procedure (Figures 9 and 10). A variety of energy sources may be used to provide energy to the electrodes, including RF, microwave and laser energy, or a combination of these (col. 6, lines 35-47). Also, Gough et al teach that the device may be operated in either a monopolar or a bipolar mode and may be switched between the two modes (col. 7, lines 40-45). It is noted that many of the claims include recitation of the device "configured to" perform various functions. This language is not deemed to present any specific structure or means supportive of the recited functions, and the Gough et al system is deemed to be capable of performing these functions.

While Gough et al disclose the use of multiple energy sources connected to the plurality of electrode/sensor members, there is no explicit disclosure that each electrode/sensor member is connected to a separate energy source. First, the

examiner maintains that the Gough et al disclosure is as explicit as applicant's specification with respect to this limitation (i.e. applicant's disclosure also does not explicitly disclose this feature). The examiner maintains that the Gough et al disclosure inherently suggests the use of different energy sources for each electrode/sensor member, or that the use of a separate source for each electrode/sensor member would be an obvious consideration in view of the Gough et al teaching of using a combination of sources for the electrode/sensor members.

Claims 38-42 and 45-71 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Gough et al ('484).

Gough et al provide a device substantially identical to the Gough et al ('384) device. It includes an elongate delivery device and a plurality of resilient members (16) which are deployable into tissue with curvature. The resilient members are RF electrodes which may be used to treat tissue, and the electrodes include sensors (24) for measuring tissue impedance and using that measurement to monitor the ablation of tissue and control the delivery of RF energy. A multiplexer is used to control the delivery of data between the multiple resilient members (see col. , lines 40-45). Resources are provided for using the impedance data to control the procedure (Figures 9 and 10). A variety of energy sources may be used to provide energy to the electrodes, including RF, microwave and laser energy, or a combination of these (col. 5, lines 1-12). Also, Gough et al teach that the device may be operated in either a monopolar or a bipolar mode and may be switched between the two modes (col. 7, lines

40-45). It is noted that many of the claims include recitation of the device "configured to" perform various functions. This language is not deemed to present any specific structure or means supportive of the recited functions, and the Gough et al system is deemed to be capable of performing these functions.

While Gough et al disclose the use of multiple energy sources connected to the plurality of electrode/sensor members, there is no explicit disclosure that each electrode/sensor member is connected to a separate energy source. First, the examiner maintains that the Gough et al disclosure is as explicit as applicant's specification with respect to this limitation (i.e. applicant's disclosure also does not explicitly disclose this feature). The examiner maintains that the Gough et al disclosure inherently suggests the use of different energy sources for each electrode/sensor member, or that the use of a separate source for each electrode/sensor member would be an obvious consideration in view of the Gough et al teaching of using a combination of sources for the electrode/sensor members.

Response to Arguments

Applicant's arguments filed April 12, 2004 have been fully considered but they are not persuasive.

Applicant contends that neither the Gough et al ('384) nor the Gough et al ('484) references disclose the use of separate energy sources for each sensor member. The examiner disagrees.

First, it is again noted that applicant's specification fails to explicitly teach this limitation as addressed in the earlier 35 USC 112, first paragraph rejection. Applicant's

specification at page 37 merely states that electrodes/antenna may be coupled to different frequency energy sources (line 5) and does not expressly state there is a separate source for each sensor member. Both Gough et al patents teach that the electrodes may be connected to a variety of energy sources, or a combination of energy sources. This disclosure in the Gough et al patents is deemed to be commensurate in scope with applicant's teaching of providing electrodes coupled to different energy sources. Moreover, it is again pointed out that applicant's specification does not specifically teach energy sources coupled to sensor members as set forth in the claims, but rather energy sources connected to electrodes. There is a degree of ambiguity associated with the recitation of "sensor members" connected to separate energy sources since there is no apparent need for a "sensor member" to be connected to an energy source unless it also functions as an electrode.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (703) 308-4305. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (703) 308-0994. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael Peffley
Primary Examiner
Art Unit 3739

mp
June 14, 2004